JUL - 1 2008

5. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance to the requirements of SDMA 1990 and 21 CFR 807.92.

Date prepared : February 25th 2008

The assigned 510(k) number is: K080974

5-1. SUBMITTER :

Fournitures Hospitalières Industrie
6 Rue Nobel, Z.I. de Kernévez
29000 QUIMPER - FRANCE
Tel: (+33) 2.98.55.68.95
Fax: (+33) 2.98.53.42.13

5-2. COMPANY CONTACT :

Franck HUNT, General Manager
Tel: (+33) 2.98.55.68.95

5-3. DEVICE NAME :

Trade name : TLS® Fixation System
Common name : Fixation screw and Non absorbable surgical suture
Classification name :
- Non absorbable surgical suture (Poly[ethylene terephtalate]):
  Regulation: 21 CFR 878.5000 / Procode: GAT
- Fixation screw:
  Regulation: 21 CFR 888.3040 / Procode: HWC

5-4. PREDICATE/ LEGALLY MARKETED DEVICES :

➢ **Non-absorbable suture :**

Manufacturer :	**Smith & Nephew**
Device Trade Name :	EndoButton™ Continuous Loop
510 (K) :	K980155
Date cleared :	04/01/1998

Manufacturer :	**F.H INDUSTRIE**
Device Trade Name :	Tenolig®
510 (K) :	K060367
Date cleared :	09/08/2006

➢ **Fixation screw:**

Manufacturer :	**Smith & Nephew**
Device Trade Name :	RCi™ screw
510 (K) :	K992945
Date cleared :	11/18/1999

5-5. DEVICE DESCRIPTION:

The TLS® Fixation System is composed of the following elements:

- **The TLS® screw**, used for the fixation of the TLS® tape to the bone.
- **The TLS®+ tendon fixation tape kit,** for the ACL and PCL reconstruction, to which the tendon graft is attached.
  This kit is composed of:
  - 1 non-absorbable tape : implantable,
  - 2 passing wires: non implantable, to be used to pass the tape and the attached graft through the bone tunnel,
  - 1 tape support: non implantable, to be used for the preparation of the graft.

The following table details our fixation screws and our non-absorbable surgical suture:

Products		Materials	Sizes	To be implanted
TLS® Screw		Titanium alloy	Ø10 Length 20, 25mm	Yes
TLS®+ tendon fixation tape kit	Tape	Poly[ethylene terephtalate]	Length: 60cm, Width: 6 cm	Yes
	Passing wires	Poly[ethylene terephtalate]	Length: 50 cm, Ø 0.7mm	No
	Tape support	Anodized aluminium	-	No

5-6. INDICATIONS FOR USE/ INTENDED USE:

The TLS® Fixation System is designed for the fixation of tendons graft to the femur and tibia during orthopaedic surgical procedures for Anterior Cruciate Ligament (ACL) and Posterior Cruciate Ligament (PCL) reconstructions.

5-7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

The TLS® screws and the TLS®+ tendon fixation tape have the same intended use and substantial similar indications for use as the predicate devices selected.
The products are all made of the same material (titanium alloy and polyethylene terephtalate), are available in similar diameters and lengths, with similar designs.

5-8. PERFORMANCES:

The TLS® Fixation System was tested against the EndoButton to determine if it was equivalent in strength. Tensile Strength, Stiffness and Cyclic Fatigue Testing were examined. After the testing was completed, it was determined that the TLS® Fixation System is as strong as the currently marketed EndoButton™.
Risk to health have been addressed through the specified materials, processing controls, quality assurance and compliance to the Medical Device Good Manufacturing Practices Regulations.

5-9. SUBSTANTIAL EQUIVALENCE:

The substantial equivalence of our products when compared to the selected predicate devices has been established following manufacturers' commercial documents and 510(k) submission's information available on FDA's website.

Tables of Substantial Equivalence

Characteristics	TLS® tape	ENDOBUTTON™ CL	TENOLIG®
Manufacturer	F.H. industrie	Smith & Nephew	F.H. industrie
510(k) number	Pending	K980155	K060367
Indications for Use	Used for ACL and PCL reconstruction	Used for ACL and PCL reconstruction	Indicated for surgical repair of Achille tendon ruptures by percutaneous approach
Material	Polyethylene terephtalate	Polyethylene terephtalate	Polyethylene terephtalate
Lengths	60 cm	10 to 80 cm	36 cm
Diameter	6 mm	6 to 12 mm	0,85mm
Sterilization	Gamma irradiation	Gamma irradiation	Gamma irradiation
Single Use	Yes	Yes	Yes

Characteristics	TLS® screw	Rci™ screw
Manufacturer	F.H. industrie	Smith & Nephew
510(k) number	Pending	K992945
Indications for Use	Graft fixation for ACL and PCL reconstruction	Graft fixation for ACL and PCL reconstruction
Material	Titanium alloy	Titanium alloy
Lengths	20 to 25 mm	25 to 50 mm
Diameter	10 mm	6 to 12 mm
Sterilization	Gamma irradiation	Gamma irradiation
Single Use	Yes	Yes

5-10. CONCLUSION:

Following the examination of all the above mentioned information, we can then conclude that the TLS® Fixation System composed of the TLS® screw and the TLS®+ tendon fixation tape are substantially equivalent to the selected predicate devices in terms of materials, intended use, performances, safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Fournitures Hospitalieres Industrie
% Mr. Franck Hunt
General Manager
ZI de Kernevez
6 rue Nobel
29000 Quimper
France

JUL - 1 2008

Re: K080974
Trade/Device Name: TLS® Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC, MBI, JDR
Dated: February 25, 2008
Received: April 4, 2008

Dear Mr. Hunt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4. Indications for Use

510(k) Number (if known): K080974

Device Name : **TLS® Fixation System**
This product is composed of the following elements:
- The TLS® screw,
- The TLS+® tendon fixation system
(1 tape , 2 passing wires, 1 tape support)

Indications for Use: The TLS® Fixation System is designed for the fixation of tendons graft to the femur and tibia during orthopaedic procedures for Anterior Cruciate Ligament (ACL) and Posterior Cruciate Ligament (PCL) reconstructions.

Prescription Use: __Yes__ AND/OR Over the counter Use:___No____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off)
Division of General, [illegible]
and Neurological [illegible]

510(k) Number K080974

Concurrence of CDRH, Office of Device Evaluation (ODE) Page__ of ___